CABINET FOR HEALTH AND FAMILY SERVICES Department for Public Health Division of Public Health Protection and Safety (Amendment)

902 KAR 50:033. Standards for enforcement procedures for <u>manufactured[manufacturing]</u> grade milk.

RELATES TO: KRS Chapter 13B, 217.025, 217.045[217.005-217.215], 217C.010-217C.990 STATUTORY AUTHORITY: KRS 194A.050(1), 211.180(1)(c), 217C.040, 217C.100[211.090] NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Cabinet for Health and Family Service to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.180(1)(c) authorizes the cabinet to promulgate administrative regulations for the safe handling of food and food products. KRS 217C.040 authorizes the cabinet to promulgate administrative regulations for the issuing and revocation of permits to milk producers, haulers, transfer stations, processing plants, pasteurization plants, and distributors, and to adopt separate regulations regulating Grade A milk products and milk for manufacturing purposes. [Cabinet for Human Resources to regulate milk for manufacturing purposes.] This administrative regulation sets uniform standards for the enforcement of 902 KAR 50:031 and 902 KAR 50:032 pertaining to the production, transportation, handling, sampling, examination, grading, and sale of manufactured [manufacturing] milk and milk products; inspection of dairy farms; and [, provides for] the revocation and reinstatement of producer permits.

Section 1. Enforcement Procedures for Raw Milk. (1) Sight and odor.

- (a) Bulk tank loads or individual producer milk received at a processing facility shall be examined on an organoleptic basis by the hauler or by the milk grader.
- (b) Milk shall not be received if any off odors or abnormal conditions are found which will adversely affect the finished product.
- (c) Producer milk rejected for sight and odor by a hauler or milk grader shall be [identified by coloring if in a can or] tagged with a reject tag [if in a bulk tank].
 - (2) Bacterial estimates.
- (a) At least one (1) time each month at irregular intervals, an official [a representative mixed] sample of each producer's milk shall be tested.
 - (b) Producers shall be notified of the results of all tests performed.
- 1.[(a)] A producer shall be given a notice of intent to suspend permit by the cabinet if two (2) of the last four (4) counts exceed bacterial standards specified in 902 KAR 50:031 Section 3(3).
- 2. An additional sample shall be taken within twenty-one (21) days of sending the notice, but not before the lapse of three (3) days.
- 3. A producer shall remain under notice of intent to suspend permit if two (2) of the last four (4) samples exceed the standards.
- 4.[(b)] A producer's permit shall be suspended by the cabinet if three (3) of the last five (5) samples exceed the standard.
- (c) A producer may be issued a temporary permit by the cabinet upon receipt from the producer of a satisfactory farm inspection and form DFS-7A, ["]Application for Reinstatement of Permit[", incorporated by reference].
- 1. If the sample from the first milk offered for sale is in compliance, the permit shall be[is] reinstated.

- <u>2.</u> If the sample is not in compliance, the temporary permit shall be withdrawn. [A copy of Form DFS-7A, "Application for Reinstatement of Permit", revised October 1986, is available for inspection and copying, 8 a.m. until 4:30 p.m., Monday through Friday, at the Office of the Commissioner for Health Services, 275 East Main Street, Frankfort, Kentucky 40621.]
- (d) Upon issuance of the temporary permit, the producer shall have no milk in the bulk tank produced during the period the permit was suspended unless specified by the cabinet. Three (3) samples shall then be taken at the rate of not more than two (2) per week on separate days within a three (3) week period.
- (e) The cabinet may reinstate the producer's permit upon receipt of a bacteria sample in compliance with standards set in 902 KAR 50:031 Section 3(3).
 - (3) Sediment.
 - (a) [Bulk tank producers.
 - 1.] If the sediment disc is classified as #1, [er] #2, or #3 the producer's milk may be accepted.
- (b)[2.] If the sediment disc is classified #3, the [producer's milk may be accepted. The] producer shall be notified by the cabinet in writing and a second milk sample shall be collected by a certified sampler and retested on the next milk pickup.
- 1. If the second sample is classified #3, the producer shall be issued a notice of intent to suspend permit and an additional sample shall be collected and tested.
- <u>2.</u> If the additional sample fails to obtain a #1 or #2 sediment sample result, the producer's permit shall be suspended.
 - <u>3.</u> If the second sample is classified #4, the producer's permit shall be suspended.
- (c)[3-] If the sediment disc is classified as #4, the producer shall be notified by the cabinet in writing and the producer's milk sample shall be collected by a certified sampler and retested on the next milk pickup. If the retest of this sample fails to obtain a #1 or #2 sediment sample result, the producer's permit shall be suspended.
- (d)[4.] The permit suspension shall be in effect until a #1 or #2 sediment test is obtained and upon receipt by the cabinet of an ["]Application for Reinstatement of Permit["].[
 - (b) Can producers.
 - 1. If the sediment disc is classified as #1 or #2, the producer's milk may be accepted.
- 2. If the sediment disc is classified #3, the producer's milk may be accepted. The producer shall be notified by the cabinet in writing and a second milk sample shall be collected by a certified sampler and retested on the next milk pickup. If the second sample is classified #3, the producer shall be notified and additional samples shall be collected and tested. If the additional samples fail to obtain a #1 or #2 sediment sample result on two (2) consecutive samples, the producer's permit shall be suspended.
- 3. If the sediment disc is classified as #4 the milk shall be rejected and an approved color added to the milk. The producer shall be notified by the cabinet in writing and the producer's milk sample shall be collected by a certified sampler and retested on the next milk pickup. If the retest of this sample fails to obtain a #1 or #2 sediment sample result, the producer's permit shall be suspended.
- 4. The permit suspension shall be in effect until a #1 or #2 sediment test is obtained and upon receipt by the cabinet of an "Application for Reinstatement of Permit".]
 - (4) Abnormal milk.
- (a) [Each producer shall be tested] At least four (4) times each six (6) months an official sample of each producer's milk shall be tested for somatic cell count.
- (b) The producer shall be notified in writing of [and those] tests showing a somatic cell count in excess of the standard specified in 902 KAR 50:031 Section 3(5).

- (c)[1,000,000/ml shall be notified in writing by the cabinet.] If two (2) of the last four (4) somatic cell counts exceed this standard[1,000,000/ml], the producer shall be given a notice of intent to suspend their permit by the cabinet.
- 1. The producer shall remain under notice if two (2) of the last four (4) samples exceed the limit; and
- 2. [-]An additional sample shall be collected within twenty-one (21) days after issuance of the notice of intent to suspend permit, but not before the lapse of three (3) days.
- (d) A producer's permit shall be suspended by the cabinet if three (3) of the last five (5) somatic cell counts exceed the limit.
- (e) Upon receipt of an [-]Application for Reinstatement of Permit[-], a sample shall be analyzed. If the sample is in compliance, the permit shall be[is] reinstated.
- (f) Three (3) samples shall be taken at the rate of not more than two (2) per week on separate days within a three (3) week period.
 - (5) Drug residues.
- (a) All marketed milk shall be sampled prior to processing using approved screening procedures defined in 902 KAR 50:031 Section 3(6).
- 1. If the presence of drug residue is detected, a confirmatory test approved by the cabinet shall be performed.
- <u>2.</u> If the confirmatory test result is positive for drug residue, the milk shall be disposed of either in a manner that removes it from the human and animal food chain or acceptably reconditioned for animal food as determined by the cabinet.
- <u>3.</u> If a commingled sample is positive, each <u>producer's milk[producer]</u> represented in the sample shall be tested immediately.
- (b) All positive drug residue sample results shall be reported to the [Cabinet for Human Resources,] Milk Safety[Control] Branch, Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621.
- (c) Milk for manufacturing permit shall be suspended upon confirmed positive drug residue sample.
- 1. First suspension within a twelve (12) month period shall require a two (2) day minimum loss of milk or equivalent as determined by the cabinet.
- 2. Second suspension within a twelve (12) month period shall require a four (4) day minimum loss of milk or equivalent as determined by the cabinet.
- 3. Third suspension within a twelve (12) month period shall require a four (4) day minimum loss of milk or equivalent as determined by the cabinet. [The cabinet shall initiate administrative procedures to revoke the producer's permit by proceeding to an informal hearing.]
- (d) The milk for manufacturing permit shall be temporarily reinstated for fourteen (14) days if a negative drug residue sample of raw milk is reported to the cabinet, and the cabinet is in receipt of an [-]Application for Reinstatement of Permit[-].
- 1. The milk for manufacturing permit shall be reinstated after the cabinet receives a copy of the ["]2019 Milk and Dairy Beef Residue Prevention Producer's Protocol" Completion Certificate of Participation signed by the producer and his veterinarian. [The "Milk and Dairy Beef Residue Prevention Protocol", 1993 Producer Manual, is published by Agri-Education, Inc., 801 Shake-speare Avenue, Stratford, Iowa 50249. The "Milk and Dairy Beef Residue Prevention Protocol", revised October 1, 1992, is incorporated by reference, and a copy is available for inspection and copying, 8 a.m. until 4:30 p.m., Monday through Friday, at the Office of the Commissioner for Health Services, 275 East Main Street, Frankfort, Kentucky 40621.]
- 2. Failure to return the completion certificate within fourteen (14) days of the temporary reinstatement shall result in a minimum one (1) day temporary permit suspension.
 - (6) Excessive water.

- (a) Milk producers with supplies found to contain at least ten (10) percent excessive water shall be issued a permit suspension requiring the supply to be withheld from sale immediately. Milk from this supply shall not be sold and the permit shall not be reinstated until a sample is negative for excessive water, and the cabinet is in receipt of an "Application for Reinstatement of Permit".
- (b) Milk producers with supplies found to contain at least two (2) percent and less than ten (10) percent excessive water shall be notified of adulteration and retested after the lapse of three (3) days. If the retested sample continues to show at least two (2) percent and less than ten (10) percent excessive water, the producer's permit shall be suspended. Milk shall not be sold from this supply and the permit shall not be reinstated until a sample is negative for excessive water, and the cabinet is in receipt of an "Application for Reinstatement of Permit".
- (c) Milk producers with supplies found to contain at least five-tenths (.5) percent but less than two (2) percent excessive water shall be notified. If the following sample shows at least five-tenths (.5) percent and less than two (2) percent excessive water, a supervised sample shall be collected. The supervised sample shall be used as a future reference for the accurate freezing point for the supply.
 - (7) Chemical contaminants.
- (a) If laboratory results of an individual producer sample show a violation of an established tolerance level for a particular chemical contaminant, the supply shall be withheld from the market channels. The producer shall be notified immediately and confirmed in writing by the cabinet.
- (b) Continued sampling of an excluded [milk] producer's supply shall be maintained until an acceptable level of the contaminant is attained. The frequency of additional sampling may be at seven (7), fifteen (15), thirty (30), or sixty (60) day intervals, depending on the laboratory workload and the previous contaminant level. Higher chemical contaminant levels shall be sampled at lesser frequencies.
- (c) If levels based on an official sample fall below acceptable tolerance levels, the producer shall be notified immediately and confirmed in writing by the cabinet that the supply is again acceptable for sale.
- (d) Producer assistance in testing individual cows, feeds, and water supplies may be obtained on an unofficial basis from the Kentucky Diagnostic Laboratories and commercial laboratories.]
- Section 2. Manufacturing Milk Producer Permit Suspension and Reinstatement. <u>In addition to the penalties established in KRS 217C.990</u>, the cabinet may suspend or revoke an individual producer's permit, in accordance with KRS 217C.040.
 - (1) The cabinet shall, upon notice to the producer, immediately suspend the permit if:
 - (a) There is reason to believe that an imminent public health hazard exists;
- (b) The producer or an employee has interfered with the cabinet in the performance of the cabinet's duties; or
 - (c) The producer or an employee has falsified any records or documents.
- (2)(a) In accordance with KRS 13B.070(3), a producer whose permit has been suspended three (3) times within a twelve (12) month period for a violation of any type in accordance with 902 KAR 50:031, 902 KAR 50:032, or this administrative regulation, shall be issued a notice that upon the fourth suspension within a twelve (12) month period the producer shall appear at the cabinet for a conference to show cause why the permit should be reinstated.
- (b) Upon the fourth suspension within a twelve (12) month period, the producer shall appear before the cabinet to show cause why the permit should be reinstated.
- (c) At this conference the cabinet may set conditions under which the permit may be reinstated.

- (d) This permit suspension shall remain in effect until the conditions of the conference have been met.
- (3) In all other instances of violation of 902 KAR 50:031, 902 KAR 50:032, or this administrative regulation, the cabinet shall:
 - (a) Serve on the producer a written notice stating the violation; and
 - (b) Afford the producer a reasonable opportunity to correct the violation.
- (4) A producer whose permit has been suspended may, at any time, submit an Application for Reinstatement of Permit.
- (5) Suspension of a permit shall remain in effect until the violation has been corrected to the satisfaction of the cabinet.
- (6) For serious or repeated violations of any of the requirements of 902 KAR 50:031, 902 KAR 50:032, or this administrative regulation the producer's permit may be permanently revoked.
- (7) Prior to revocation, the cabinet shall notify the producer in writing, stating the reasons for which the permit is subject to revocation and advising the permit shall be permanently revoked at the end of ten (10) days following the service of the notice, unless the Request for Hearing is filed with the Milk Safety Branch.
 - (8) The hearing shall be conducted in accordance with KRS 217C.100.
 - Section 3. Incorporation by Reference. (1) The following material is incorporated by reference:
 - (a) "2019 Milk and Dairy Beef Residue Prevention Producer's Certificate of Participation";
 - (b) "Application for Reinstatement of Permit", DFS-7A, 4/2020; and
 - (c) "Request for a Hearing", DFS 8, 4/2020.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at Milk Safety Branch, Division of Public Health Protection and Safety, Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.[An individual producer's permit shall be suspended if the cabinet has reason to believe that a public health hazard exists; the producer has violated any of the requirements of 902 KAR 50:031, 902 KAR 50:032, or this administrative regulation; or the producer has interfered with the cabinet in the performance of its duties. The cabinet shall in all cases, except if the milk involved creates, or appears to create, an imminent hazard to the public health; or in any case of willful refusal to permit authorized inspection, serve upon the producer a written notice of intent to suspend the permit. This notice shall specify the violation in question and afford the permit holder reasonable opportunity to correct the violation. Suspension of a permit shall remain in effect until the violation has been corrected to the satisfaction of the cabinet.
- (2) If the producer's permit has been suspended three (3) times within a twelve (12) month period for a violation of any type in accordance with 902 KAR 50:031, 902 KAR 50:032, or this administrative regulation, the producer shall be issued a notice that upon the fourth suspension within a twelve (12) month period the producer shall appear at the cabinet for a conference to show cause why the permit should be reinstated. Upon the fourth suspension within a twelve (12) month period, the producer shall appear before the cabinet to show cause why the permit should be reinstated. At this conference the cabinet may set conditions under which the permit may be reinstated. This permit suspension shall remain in effect until the conditions of the conference have been met. If a fifth suspension occurs within a twelve (12) month period, the cabinet shall proceed to a hearing. At this hearing the producer shall have the opportunity to show cause why the permit should not be permanently revoked, and the cabinet shall affirm, modify, or rescind the producer's permit.
- (3) Upon written application of any person whose permit has been suspended, or upon application within forty-eight (48) hours of any person who has been served with a notice of intention

to suspend, and in the latter case before suspension; the cabinet shall, within a reasonable time, proceed to hearing to ascertain the facts of the violation or interference.

- (a) The request for a hearing shall be made in writing on Form DFS-8, "Request for Hearing", revised January 1989, incorporated by reference. Form DFS-8, "Request for Hearing", may be viewed or obtained, 8 a.m. until 4:30 p.m., Monday through Friday, at the Office of the Commissioner of Health Services, 275 East Main Street, Frankfort, Kentucky 40621.
 - (b) The cabinet shall notify the requesting party in writing of the:
 - 1. Name of the hearing officer; and
 - 2. Time and place of the hearing.
- (c) All parties shall be allowed a reasonable time to prepare for the hearing, including the right to:
 - 1. Be represented by counsel;
 - 2. Present evidence on his behalf; and
 - 3. Cross-examine witnesses.
- (d) A transcript of the hearing shall not be made unless requested. The expense of transcribing the hearing shall be the responsibility of the requesting party.
- (e) The hearing officer shall make written findings of fact and conclusions of law, and render a decision based upon the evidence presented. The decision of the hearing officer shall be the final decision of the cabinet.
- (4) Any permit suspended under the provisions of 902 KAR 50:031, 902 KAR 50:032, or this administrative regulation may be reinstated by submission of satisfactory evidence to the cabinet that the violation has been corrected.]

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: July 9, 2020

FILED WITH LRC: July 15, 2020 at 9 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on September 28, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by September 21, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until September 30, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Donna Little

(1) Provide a brief summary of:

- (a) What this administrative regulation does: This administrative regulation sets uniform standards for the enforcement of 902 KAR 50:031 and 902 KAR 50:032 and provides for the revocation and reinstatement of producer permits.
- (b) The necessity of this administrative regulation: KRS 217C.040 authorizes the secretary to adopt rules and regulations regulating the issuing and revocation of permits to milk producers, haulers, transfer stations, processing plants, pasteurization plants, and distributors. KRS 217C.100 requires all administrative hearing conducted pursuant to KRS Chapter 217C be conducted in accordance with KRS Chapter 13B.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes the enforcement actions including the revocation and reinstatement of milk producers permits.
- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will ensure the supply of milk and dairy products is safe for human consumption by establishing enforcement procedures for milk producers.
- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
- (a) How the amendment will change this existing administrative regulation: The amendment to this administrative regulation deletes references to the quality of milk in cans, deletes references to excessive water and chemical contaminants in the raw milk supply, updates the permit suspension and reinstatement procedures, updates the material incorporated by reference, and makes other amendments to comply with KRS Chapter 13A drafting rules.
- (b) The necessity of the amendment to this administrative regulation: The amendment to this administrative regulation is necessary to ensure the supply of milk for manufacturing, and the products made from this supply of milk, meet the highest standards for quality.
- (c) How the amendment conforms to the content of the authorizing statutes: KRS 217C.040 authorizes the secretary to adopt rules and regulations regulating the issuance and revocation of permits to milk producers, haulers, transfer stations, processing plants, pasteurization plants, and distributors. This amendment establishes the enforcement procedures for producers of milk for manufacturing whose milk does not meet the highest quality standard established in 902 KAR 50:031. KRS 217C.100 requires that all administrative hearings be conducted accordance with KRS Chapter 13B. The amendment to this administrative regulation ensures those administrative hearings procedures are followed.
- (d) How the amendment will assist in the effective administration of the statutes: The amendment to this administrative regulation will ensure the quality of milk offered for manufacturing meet the highest quality standard, and will ensure a fair and consistent process for any adverse actions taken against a producer.
- (3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Currently there are 470 registered dairy farms. This administrative regulation will impact those currently producing milk for manufacturing and those producing Grade A milk who have been downgraded due to a quality issue.
- (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
- (a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: All producers will need to be aware of the quality standard for raw milk and ensure they are meeting the standards outlined in 902 KAR 50:031.

- (b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): The cost for compliance is unknown at this time. A producer who is not in compliance with the requirements of 902 KAR 50:031 may have costs associated with upgrading equipment and processes. A producer facing permit suspension or revocation may have costs associated with complying with the orders of the cabinet to reinstate the permit.
- (c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Producers of milk for manufacturing will be able to ensure a quality product. Grade A producers who have been downgraded will continue to be able to offer milk for manufacturing while addressing the issue that resulted in the downgrade of their permit.
- (5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
 - (a) Initially: This is an ongoing program, there are no new initial costs.
- (b) On a continuing basis: Implementation of this ongoing program will not increase program costs.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Milk Safety Branch operates with approximately \$1 million from the General Fund. There are no additional costs associated with this amendment.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: An increase in fees and funding is not necessary to implement the changes to this administrative regulation.
- (8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. This administrative regulation does not contain fees.
- (9) TIERING: Is tiering applied? is not applied. All producers of milk are required to adhere to quality standards and are all subject to the same enforcement procedures when the supply of milk is out of compliance with those standards.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

- 1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Milk Safety Branch in the Division of Public Health Protection and Safety.
- 2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.050(1), 211.180(c), 217C.040, and 217C.100.
- 3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.
- (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation does not generate revenue.
- (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation does not generate revenue.
- (c) How much will it cost to administer this program for the first year? The Milk Safety Branch operates on approximately \$1 million from the General Fund. An increase in funding is not needed to implement this administrative regulation.

(d) How much will it cost to administer this program for subsequent years? The Milk Safety Branch operates on approximately \$1 million from the General Fund. An increase in funding is not needed to implement this administrative regulation.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-):

Other Explanation: